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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,550	03/29/2004	Nobuko Yamamoto	00862.023526.	1679

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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,550	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 7-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6* is/are rejected.

7)☒ Claim(s) *4-6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0208;0508*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This action is responsive to the complying complete set of claims filed April 27, 2009, the amendments to the specification filed September 30, 2008, and the arguments and remarks of May 12, 2008 and January 26, 2009.

The amendments to the specification (providing required sequence identifiers) filed September 30, 2008 have been entered.

Claims 4-6 have been amended. Claims 1-3 and 7-49, as well as sequences other than elected SEQ ID NO: 1, remain withdrawn from consideration (see also paragraphs 3-4 below). Accordingly, claims 4-6 remain under consideration herein.

Applicant's amendments to claims 4-6 have overcome the objections to those claims set forth in paragraphs 4-6 of the Office action of January 10, 2008, as well as the rejection of claim 4 under 35 USC 112, second paragraph set forth in that Office action (paragraph 10).

Regarding the rejections under 35 USC 102 set forth in the prior Office action of January 10, 2008, Applicant's amendments and arguments have been thoroughly reviewed, but are moot in view of the new grounds of rejection under 35 USC 103 set forth below. The new grounds were necessitated by applicant's amendment of the claims under consideration to require probes "consisting of" elected SEQ ID NO: 1 or its complement. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

3. Applicant's election without traverse of Group I, and of SEQ ID NO: 1, in the reply filed on November 2, 2007 is again acknowledged. Claims 4-6 (to the extent that they are drawn to SEQ ID NO: 1) remain under consideration.

4. Claims 1-3 and 7-49, as well as sequences other than elected SEQ ID NO: 1, remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 2, 2007.

5. Applicant's request for rejoinder of claim 7 upon the allowance of claim 6 (see page 13 of the Remarks of May 12, 2008) is noted. No claims are presently in condition for allowance.

Claim Objections

6. Claims 4-6 remain objected to because the claims encompass non-elected subject matter, specifically, SEQ ID NOs other than elected SEQ ID NO: 1. The claims should be amended such that they are drawn only to the elected invention. Applicant's comment with regard to the objection (at page 12 of the Remarks of May 12, 2008) is noted. The objection is maintained at the present time because the claims continue to encompass non-elected sequences.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANT'S AMENDMENTS:

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

The claims have been amended such that they are drawn to a probe or probes consisting of an "oligonucleotide and optionally a label" wherein "the oligonucleotide consists of the base sequence of" SEQ ID NO: 1 or the complement thereof. However, while the originally filed specification teaches a probe consisting of SEQ ID NO: 1 or its complement, it does not provide basis for the inclusion of a label. It is noted that applicant has not provided any indication as to where basis is believed to be found for this new limitation. A review of the specification reveals basis for the labeling of a specimen/target for probe detection via PCR amplification (see, e.g., pages 12, 21-22 [including Table 11], 29, 39, and 46-47), including an embodiment employing a labeled reverse primer (see page 47, as well as the primers disclosed in Table 11 on page 22). However, the specification does not disclose the particular labeled probe now encompassed by the claims, nor does the specification include, e.g., a general disclosure of labeling or "optionally labeling" the "detection probes" of the invention. Accordingly, applicant's amendment introduces new matter.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu et al (US 2004/0010129 A1 [15 January 2004; filed 28 October 2002]) in view of Hogan et al (US 6,376,186 B1 [23 April 2002; filed 3 May 2000]).

Hsu et al disclose a set of probes "for diagnosing *Staphylococcus aureus*," which probe set includes probes comprising instant SEQ ID NO: 1 (see entire reference, particularly, page 2 paragraphs 13 and 15 [noting the sequence identified as "1-2", as well as claim 2). With further regard to claim 6, Hsu et al disclose biochips comprising their probe sets; see, e.g., paragraphs 18-19 and

52, and claims 23-25 and 28). Therefore, Hsu et al describe a probe, a probe set and a carrier differing from the claimed invention only with respect to the length of the probe. Specifically, applicant's claimed probe of SEQ ID NO: 1 is 6 nucleotides shorter than the probe of Hsu et al, as SEQ ID NO: 1 constitutes nucleotides 4-29 of Hsu et al's 32-nucleotide probe.

Hogan et al teach a variety of different probes for detection and quantitation of Staphylococcus species (see entire reference). Hogan et al disclose the use of probes of up to 100 nucleotides in length that include "at least 17 contiguous nucleotides" of a target staphylococcal sequence, as well as probes "from 17-60 nucleotides in length" (see, e.g., col 2, line 30-col 3, line 47; col 8, lines 39-54). Hogan et al provide "general guidelines" that can be "used for designing probes having desirable characteristics," and particularly suggest designing probes that are appropriate for the conditions of a particular assay, and the avoidance of probes "having extensive self-complementarity" (see col 9, line 56-col 11, line 38). Hogan et al also teach a preferred probe length of 15-50 nucleotides wherein the probes are "sufficiently homologous to the target nucleic acid to permit hybridization under high stringency conditions" (see col 11, lines 25-38).

In view of the teachings of Hogan et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the probe of Hsu et al so as to have removed 3 nucleotides from each end of that probe and thereby to have prepared the probe of the instant claims. Hogan et al disclose that probes of a variety of lengths within the range

of 15-50 or 17-60 nucleotides may be employed in detecting staphylococci, and teach that probes may be designed and/or modified to allow for hybridization under the assay conditions that a practitioner wishes to use. Thus, an ordinary artisan would have been motivated to have lengthened or shortened the probes of Hsu et al as necessary to produce probes more desirable for use in a particular assay. More particularly, an ordinary artisan would have been motivated to have employed a shorter probe, such as the probe of the claims, when performing an S. aureus detection assay utilizing a lower temperature and/or otherwise less stringent conditions, for the advantage of, and to achieve the predictable result of, allowing specific bacterial detection under the conditions being employed. Additionally and/or alternatively, it is noted that the regions at each end of Hsu et al's probe encompass sequences that share self-complementarity with regions located in the center of Hsu et al's probe; see the underlined regions in "A" below with respect to the 5' end of the probe, and the highlighted regions in "B" below with respect to the 3' end of the probe:

A. 5'-TTTGAACCGCATGGTTCAAAAGTGAAAGACGG-3'

B. 5'-TTTGAACCGCATGGTTCAAAAGTGAAAGACGG-3'

Accordingly, an ordinary artisan would have been motivated to have made such a modification for the advantage of reducing regions of self-complementarity in the probe of Hsu et al and thereby to have increased the likelihood of successful target detection, as is explicitly taught by Hogan et al.

With further regard to claim 4, it is noted that Hsu et al teach that their probe may be used to differentiate S. aureus from each of the types of bacteria

recited in claim 4 (see, e.g., paragraph 13 of Hsu et al). Further, the instant claims merely require that the claimed probe "can detect an existence of a 16s rRNA gene originating" in S. aureus in a sample which may contain one or more of the recited bacteria; thus, the claims encompass detection performed under any conditions of a practitioners choosing. Accordingly, one of ordinary skill in the art would have had a reasonable expectation that the probe suggested by Hsu et al in view of Hogan et al could be employed successfully in the manner recited in the claim, such that the probe suggest by the references meets this claim limitation. With regard to claims 5-6, the claims also merely require that the claimed probe "can detect an existence of a 16s rRNA gene originating" in S. aureus under any conditions of a practitioner's choosing. Thus, an ordinary artisan would also have had a reasonable expectation that the probe suggested by Hsu et al in view of Hogan et al could be employed successfully in the manner recited in the claim, such that the probe suggest by the references meets this claim limitation.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571/272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634